

subject a composition comprising a therapeutically effective amount of a supercritical CO₂ neem extract (SCNE), wherein the SCNE comprises nimbolide, nimbin and salinin.

66. The method of claim 65, further comprising a pharmaceutically acceptable excipient.

67. The method of claim 65, wherein the subject is a human.

68. The method of claim 65, wherein the subject has been diagnosed with a need for treatment of a disorder of uncontrolled cellular proliferation prior to the administering step.

69. The method of claim 68, further comprising the step of identifying a subject in need of treatment of a disorder of uncontrolled cellular proliferation.

70. The method of claim 69, wherein the disorder of uncontrolled cellular proliferation is a cancer.

71. The method of claim 70, wherein the cancer is colon cancer.

72. A process for preparation of standardized CO₂ extract of *Azadirachta indica* leaves comprising:

- a) powdering the clean and matured dried *Azadirachta indica* leaves having moisture content less than 12% to obtain powder with fine particles having size below 0.42 mm;
- b) subjecting the powder of step a) to supercritical CO₂ extraction at a pressure varying between 80 Bar (80 kg/cm²) and 350 Bar (350 kg/cm²) at a temperature range of 31° C. to 45° C. at a flow rate of 10 to 40 kg of CO₂ per kg of raw material;
- c) separating the CO₂ extractives at a pressure varying between 40 Bar to 65 Bar at a temperature lower than the extraction temperature to obtain Extract A;
- d) subjecting the remaining residual powder after separating Extract 'A' to further extraction using mixture of CO₂ and ethyl alcohol at the pressure ranging between 80 Bar to 350 Bar and at a temperature range of 31° C. to 45° C.;
- e) collecting the ethyl alcohol laced with extract from separator by reducing the solvent pressure between 40 Bar and 65 Bar at a temperature lower than the extraction temperature, followed by vacuum distillation of ethanol to obtain Extract B; and
- f) combining Extract A and Extract B to obtain standardized CO₂ extract of *Azadirachta indica* leaves.

73. The process as claimed in claim 72, wherein the extract A is optionally subjected to high velocity micro-jet or nozzle to get a particle size of 10 nm-100 nm.

74. The process as claimed in claim 72, wherein the ethyl alcohol is used in an amount of 3 to 10% of the CO₂.

75. The process as claimed in claim 72, wherein, the separation temperature in step c) and collection temperature in step e) is maintained between 10° C. to 30° C.

76. The process as claimed in claim 72, wherein, the vacuum distillation of ethanol is carried at temperature below 45° C.

77. The process as claimed in claim 72, wherein, the standardized extract obtained in step f) comprises nimbolide in a minimum amount of 3 mg/gm; nimbin in a minimum amount of 130 µg/gm and salinin in a minimum amount of 200 µg/gm.

78. A standardized CO₂ extract of *Azadirachta indica* comprises nimbolide in a minimum amount of 3 mg/gm; nimbin in a minimum amount of 130 µg/gm and salinin in a minimum amount of 200 µg/gm.

79. The standardized extract as claimed in claim 78, wherein, the extract further contains various other active phytoconstituents such as desacetylnimbin, azadiradione, azdirone, nimbolin, and nimbinene in minor amounts.

80. A therapeutic herbal composition comprising standardized CO₂ extract of *Azadirachta indica* as claimed in claim 78 or claim 79 in an effective amount of 50 to 300 mg along with one or more pharmaceutical carriers/excipients.

81. The herbal composition as claimed in claim 80, wherein the extract comprises nimbolide in a minimum amount of 3 mg/gm; nimbin in a minimum amount of 130 µg/gm and salinin in a minimum amount of 200 µg/gm along with other active phytoconstituents, desacetylnimbin, azadiradione, azdirone, nimbolin, and nimbinene in minor amounts.

82. The herbal composition as claimed in claim 80, wherein the pharmaceutical excipients/carriers are selected from the group consisting of distilled water, saline, aqueous glucose solution, alcohol (e.g., ethanol), surfactants, propylene glycol, tween-80 and polyethylene glycol; and oily carriers such as various animal and vegetable oils, white soft paraffin, paraffin, wax, glucose, fructose, sucrose, maltose, yellow dextrin, malt dextrin, white dextrin, aerosol, micro-crystalline cellulose, calcium stearate, magnesium stearate, sorbitol, stevioside, corn syrup, lactose, citric acid, tartaric acid, malic acid, succinic acid, lactic acid, L-ascorbic acid, dl-alpha-tocopherol, glycerin, propylene glycol, glycerin fatty ester, poly glycerin fatty ester, sucrose fatty ester, sorbitan fatty ester, propylene glycol fatty ester, *acacia*, carrageenan, casein, gelatin, pectin, agar, vitamin B group, nicotinamide, calcium pantothenate, amino acids, aerated or fumed silica, calcium salts, pigments, flavors and preservatives.

83. The herbal composition as claimed in claim 80, wherein the composition can be formulated into oral solid or liquid dosage forms.

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